Docket No. HRT0144CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donlon et al.

Serial No. : Art Unit:

Filed : Examiner:

For : Less-Invasive Devices and Methods for Cardiac

Valve Surgery

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September 15, 2003
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Brian S. Tomko
(Name of applicant, assignee, or Registered Representative)

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Commissioner for Patents Washington, D.C. 20231

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Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

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Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under \$1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under \$1.114, no additional fee is required.

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required to to the state of the	est. es of references listed on the attached Form 1449 were previously cited by or submitted the Patent and Trademark Office in prior ication Serial No. 09/416,492, filed October 1999, which is a continuation of lication Serial No. 08/594,870, filed

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January 31,1996, now U.S. patent No. 6,010,531, which is a continuation-in-part of Serial No. 08/485,600, filed June 7, 1995, now abandoned, which is a continuation-in-part of Serial No. 08/281,962, now abandoned, which is a continuation-in-part of Serial No. 08/163,241, now U.S. Patent No. 5,571,215, which is a continuation-in-part of Serial No. 08/023,778, now U.S. Patent No. 5,452,733. This application is also a continuation-in-part of Serial No. 08/486,941, now U.S. Patent No. 5,799,661. There are no listed references which are not in the The relevance of those listed references which are

English language.

Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

not in the English language is as follows:

Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/HRT144CON/BST. This form is submitted in triplicate.

Respectfully submitted,

Brian S. Tomko Reg. No. 41,349

Attorney for Applicants

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-1239

DATED: September 15, 2003

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	Application Number					
	Filing Date					
	First Named Inventor	Donlon				
	Group Art Unit	3738				
	Examiner Name	D. Isabella				
	Attorney Docket Number	HRT-0144CON				

				U.S. PATENT DOCUMENTS		
	U.S. Patent Document Name of Patentee or Applicant Date of Publication Pages, Columns, Lines					
Examiner Initials	Cite No. ¹	l .	d Code ² known)	Name of Patentee or Applicant of Cited Document	of Cited Document mm-dd-yyyy	where relevant passages or relevant figures appear
		RE35,352		Peters	10/96	
		3,409,013		Berry	11/68	
		3,587,115		Shiley	6/71	
		4,056,854		Boretos et al.	11/77	
		4,065,816		Sawyer	1/78	
		4,173,981		Mortensen	11/79	
		4,185,636		Gabbay et al.	1/80	
		4,562,832		Wilder et al.	1/86	
		4,585,453		Martin et al.	4/86	
		4,602,911		Ahmadi et al.	7/86	
		4,655,218		Kulik et al.	4/87	
		4,679,556		Lubock et al.	7/87	
		4,808,163		Laub	2/89	
		4,877,016		Kantor et al.	10/89	
		5,011,481		Myers et al.	4/91	
		5,032,128		Alonso	7/91	
		5,041,130		Cosgrove et al.	8/91	
		5,104,407		Lam et al.	4/92	
		5,109,859		Jenkins	5/92	
	 	5,188,619		Myers	2/93	
•		5,197,979		Quintero et al.	3/93	
		5,203,776		Durfee	4/93	
		5,209,747		Knoepfler	5/93	
	1	5,213,093		Swindle	5/93	
		5,236,450		Scott	8/93	
	1	5,250,038		Meiker et al.	10/93	
		5,306,234		Johnson	4/26/94	
		5,308,320		Safar et al.	5/94	
	T	5,332,402		Teitelbaum	7/94	
	1	5,383,888		Zvenyatsky et al.	1/95	
	†	5,391,156		Hildwein et al.	2/95	
	1	5,423,887		Love et al.	6/95	
	 	5,433,700		Peters	7/95	
	,		<u> </u>	J	1	1

5,443,446	Shturman	8/95	
5,452,733	Sterman et al.	9/95	
5,458,574	Machold et al.	10/95	
5,478,309	Sweezer et al.	12/95	
5,536,251	Evard et al.q	7/96	
5,545,214	Stevens	8/96	
5,556,412	Hill	9/96	
5,560,487	Starr	10/96	
5,578,076	Krueger et al.	11/96	
5,613,937	Garrison et al.	3/97	
5,626,607	Malecki et al.	5/97	
5,682,906	Sterman et al.	11/97	
5,702,368	Stevens et al.	12/97	

FOREIGN PATENT DOCUMENTS

Examiner	Cite	Foreign Patent Document Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶			
Initials	No.1	Office ³	Number⁴ Kir	ndCode ⁵		<u> </u>	ilgules appeal	
		EP	0 218 275			4/1987		
		FR	2681775			4/1993		
		wo	87/05489			9/1987		
{		wo	93/20742			10/93		
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	First Named Inventor	Donlon				
	Group Art Unit	3738				
	Examiner Name	D. Isabella				
	Attorney Docket Number	HRT-0144CON				

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item							
Examiner's	Cite	(book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	T ²				
Initials*	No.1	publisher, city and/or country where published					
		Berreklouw et al. "Revival of Right Thoracotomy to Approach to Atrio-ventricular Valves in Reoperations" Thorac Cardiovasc	l				
	 	Surgeon (1984)32:331-333					
	 	Duran, C. "Present Status of Reconstructive Surgery for Aortic Valve Disease" J Card Surg (1993) 8:443-452. Hirose et al., "Another Approach for Aortic Valve Replacement Through Left Thoracotomy", Ann Thorac Surg, 1994;58:884-					
		86					
		Meditech, Instructions for Use, Occlusion Balloon Catheters Rev. Mar. 1991, pp. 1-7.					
		Kon et al., "Comparison of Implantation Techniques Using Freestyle Porcine Aortic Valve", Ann Thorac Surg, 59:857-62 (1995)					
		Cosgrove, D.M. "Management of the Calcified Aorta: An Alternative Method of Occlusion" Ann Thorac Surg. (1983) 36:718-719.					
		J.H. Foster and J.B. Threlkel "Proximal Control of Aorta with a Balloon Catheter" Surg. Gynecology & Obstretrics (1971) pp. 693-694.					
		H. G. Erath, Jr. and William S. Stoney, Jr. "Balloon Catheter Occlusion of the Ascending Aorta: Ann Thorac surg. (1983) 35:560-561					
		Sakaguchi et al. "Aortic Valve Replacement and Coronary Artery Bypass" J. Japaneswe Assoc. for Thoracic Surgery (1993) 41(6):1063-1068.					
		Coltharp, William H. et al., "Videothorascopy" Ann Thorac Surg (1992) 53:776-9.					
		Jamieson, W.R. Eric "Modern Cardiac Valve devices-Bioprostheses and Mechanical Prostheses" J. Card surg (1993) 8:89-98					
		Landreneau et al., "Video-assisted Thoracic Surgery" Ann Thorac Surg (1992) 54:800-7.					
		Mack et al. "Present Role of Thoracoscopy in the Diagnosis and Treatment of Diseases of the Chest" Ann Thorac surg (1992) 54:403-9.					
		Magovern, George J. "Sutureless Aortic and Mitral Prosthetic Valves" J Thoracic and Cardiovasc Surg. (1964) 48(3): 346-361.					
		Ozuner et al. "Creation of a Pericardial Window using Thoracoscopic Techniques" Sur. Gynecology & Obstretrics (1992) 175:69-71.					
		Rao and Kumar, Aortic Valve Replacement through Right Thoracotomy, Texas Heart Institute Journal, 1993;20(4):307-308					
		Wakabayashi, Ako "Expanded Applications of Diagnostic and Therapeutic Thoracoscopy" J Thorac and Cardiovasc Surg (1991 102:721-3					
		Cohn et al. "Right TGhroacotomy, Femorofemoral Bypass and Deep Hypothermia for Re-replacement of the Mitral Valve" Ann Thorac Surg (1989) 48:69-71.					
		Fundaro et al. "Towards an easier and safer reopreat of the atriventricular valves. The right anterolateral thoracotomy approach without pericardial dissection" J. Cardiovasc Surg (1989) 30:779-781					
		Tribble et al. "Anterolateral Thoracotomy as an Alternative to Repeat Median Sternotomy for Replacement of the Mitral Valve" Ann Thorac Surg (1987) 43:380-382					
							
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